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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,719	11/17/2003	Janel E. Young	ETH5095	2358

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EXAMINER
FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
06/08/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/714,719	YOUNG ET AL.	
	Examiner	Art Unit	
	BLESSING M. FUBARA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/26/09*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The request for reconsideration after the Final rejection of 2/24/09 has been carefully considered. While page 8, lines 2-7 of the office action of 8/19/08 fully addressed applicant's reference to page 5, lines 14-16 and 23-26, Example 3 at pages 33 and 34; the office action of 2/24/09 did not refer applicant to the office action of 8/19/08 as having responded to the very same reference of unexpected result applicant has referred to on page 10, last paragraph to page 11, line 5 of the response filed 5/22/08. Therefore, applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

No claims are amended with the filling of 5/26/09. Claims 1 and 13 were amended on 11/19/09. Withdrawn claims 14-41 were canceled 11/19/09. Claims 1-13 are pending.

Response to Arguments

Previous rejections that are not reiterated herein are withdrawn in view of the amendment to claims 1 and 2 and the cancellation of claims 1-13 of copending Application No. 10/797,367 in the response filed 5/22/08.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adachi et al. ("The prevention of Postoperative Intraperitoneal adhesions by Tranilast: N-(3',4'-dimethoxycinnamoyl) Anthranilic Acid) in Jpn. J. of Surg., (1999), 29, 51-54) in view of Sheffield et al. (US 4,937,254).

4. Adachi describes how to prevent postoperative intraperitoneal adhesions by oral administration of composition comprising tranilast and carboxymethylcellulose prior to and after surgery (see the whole document with emphasis on the abstract and page 52). The carboxymethylcellulose meets the limitation of delivery vehicle of claim 1. Therapeutically effective amount as recited in claim 1 is any amount deemed effective by the artisan. Administration of 60 mg/kg per day represents a single dose as recited in claim 8 and also meets the limitation of claim 11. The carboxymethyl cellulose is a sustained release excipient so that the composition administered is in sustained release form meeting claims 9 and 10. The oral administration of tranilast composition prior to surgery meets the limitations of systemic administration and thus meets claims 12 and 13. The melted tranilast and the carboxymethylcellulose are in solution form so that the carrier composition in claim 3 is met.

5. Adachi does not teach that the composition comprising tranilast is locally administered to tissue at surgical sites to treat adhesions. But, local and/or topical administration of therapeutic

agents at surgical sites to treat or inhibit adhesion formation is known for various agents. For example:

6. Sheffield discloses method of inhibiting the formation of post surgical adhesion by administration of compositions to the site of surgical trauma to inhibit the post surgical adhesion (abstract; column 2, lines 34-38; column 3, lines 15-28, 39-56). The composition locally or topically administered at the surgical site comprises non-steroidal anti-inflammatory drug (NSAID) and pharmaceutically acceptable carrier (column 4, lines 12-29); when the composition is carried in a liposome or when the NSAID is encapsulated in a microcapsule, the composition of Sheffield meets the requirements of claim 3; when the polymeric carriers is lactide, the composition of Sheffield meets the requirements of claim 4. Furthermore, Sheffield teaches that the composition can be applied by catheterization using implanted osmotic pump (column 3, lines 29-38) so that when the delivery method is by osmotic pump, the requirement of claim 3 is met.

7. Therefore, taking the teachings of Adachi and Sheffield, one having ordinary skill in the art at the time the invention was made would have reasonably expectation of success that topical or oral administration anti-adhesion composition of Adachi or Sheffield or the combined composition of Adachi and Sheffield would produce the expected inhibition of post surgical adhesion.

8. When the composition of Adachi and Sheffield are combined, the composition having tranilast and anti-inflammatory agent meets claims 2, 5 and 6 with the topical administration meeting requirements of claim 2. With regards to claim 7, the basic structure of the analogs is

related to the core structure of the tranilast so that it flows that the activities of the analogs and the tranilast would be the same.

Response to Arguments

9. Applicant's arguments filed 5/26/09 as they apply to the current rejections have been fully considered but they are not persuasive.

10. Applicant argues that the finality of the last office action was improper because the amendment was made in response to formal rejections made in the office action of 8/19/08. But the examiner disagrees. Amendment to claim 1 indicating a composition comprising tranilast overcame the rejection under 35 USC 112, 2nd. However, in addition to said amendment, the claim was also amended to include new limitation of administration at surgical site. Thus, the new limitation of "at the surgical site" necessitated the use of a secondary reference to show that compositions are topically administered to treat post surgical adhesions. Therefore, the change in the rejection was due to the amendment to the claims requiring administration at surgical site and not due to the amendment to claim 1 indicating composition.

11. Applicant further argues that the office action is incomplete because the examiner failed to consider applicant's request of 11/19/2008 for consideration of unexpected results presented in the specification at page 5, lines 14-16 and 23-26, Example 3 at pages 33 and 34. But, the data referred to by applicant was fully addressed on page 7, lines 2-7 of the office action of 8/19/08. However, the finality of the office action of 2/24/09 is withdrawn because the examiner inadvertently omitted the response or refer to the office action of 8/19/08. It is also noted that Sheffield teaches method of inhibiting post surgical adhesion by locally administering composition comprising anti-inflammatory agent and carrier.

12. Applicant's arguments with respect to the rejections of claims 1-5 and 7-13 over Adachi in view of Hubbel is moot because of the withdrawal of the rejections in the current office action.

13. Applicant argues that Sheffield fails to suggest tranilast as an NSAID and cannot cure the deficiency of Adachi. While the examiner agrees with applicant that Sheffield does not teach tranilast, the examiner notes that Sheffield teaches method of inhibiting post surgical adhesion by locally administering composition to surgical site to inhibit the adhesion. Sheffield is relied upon for teaching that post surgical adhesion is inhibited by topical administration of compositions containing NSAID and carrier composition. Thus, post surgical adhesion is effectively treated by topical or oral administration according to Sheffield and Adachi.

14. Applciant argues that Adachi does not administer the composition directly to the surgical site. The examiner agrees with applicant and this is why the rejection is not made under 35 USC 102. A secondary reference is relied upon to show that topical administration of compositions at surgical sites is known to treat post surgical adhesions. Adachi is relevant because Adachi administers composition comprisng tranilast to treat post surgical adhesions.

15. Applicant argues by way of unexpected results that according to page 5, lines 14-16 and 23-26 and Example 3 at pages 33 and 34 and Tables 14 and 15 of the instant specification, Adachi's suggestion that post operative adhesion is treated with oral administration of composition containing tranilast is not valid. However, page 5, lines 14-16 states "…of significant note, however, ischemia via abrasion of the surgical site was not performed in the model utilized in this study," but applicant has not related the abrasion of the surgical site to the the claimed method of inhibiting post opearative adhesion. Adachi teaches inhibiting post operative adhesion and the difference between claim 1 and Adachi is that Adachi orally

administers tranilast while claim 1 topically administers tranilast containing composition. The section of the instant specification relied upon by applicant is not in the claims and is thus noted that those features upon which applicant relies (i.e., ischemia via abrasion) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). This does not represent unexpected results.

16. With regards to Example 3, pages 33 and 34, it is noted that the specific composition disclosed in said example is not the composition that is disclosed by Adachi. Moreover, topical administration of compositions to surgical site is known to the effective in inhibiting post surgical adhesion according to Sheffield. Therefore, applicant has not factually shown that the oral administration of the Tranilast composition is ineffective in inhibiting post surgical administration and moreover, applicant has not factually shown that the composition of Tranilast cannot be locally applied to surgical site.

17. Applicant argues against the references individually, and one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING M. FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Examiner, Art Unit 1618